

47371-164

3/6/2015

1/12



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 6, 2015

Liane Jenkins
Senior Regulatory Compliance Specialist
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

Subject: Label Notification per PRN 98-10 – To correct the dilution rate under Directions for Use.
Product Name: 47371-164
EPA Registration Number: Formulation HS-1210 Disinfectant/Sanitizer (50%)
Application Date: February 10, 2015
Decision Number: 500126

Dear Ms. Jenkins:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415 or Velma Noble at (703) 308-6233.

Sincerely,

A handwritten signature in black ink, appearing to read "Velma Noble".

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

2/12

Note to Reviewer:

[Items in brackets [AAA] are optional and may/may not be included on final label]

{Items in braces {AAA} are for information purposes and will not appear on final label}

FORMULATION HS-1210 DISINFECTANT / SANITIZER (50%)

[ONE-STEP DISINFECTANT]

[SANITIZER – GERMICIDE – DEODORANT]

NOTIFICATION
Date Reviewed: 05.06.2015
Reviewed By: E. O'Connell

[Salmonellacidal – Bactericidal – Pseudomonacidal – Staphylocidal – Fungicidal – *Virucidal]

Active Ingredients:

Didecyl dimethyl ammonium chloride	30.00%
n-Alkyl (C ₁₄ 50%, C ₁₂ 40%, C ₁₆ 10%) dimethyl benzyl ammonium chloride.....	20.00%
Inert [Other] Ingredients:.....	50.00%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

See [side] [right] [back] [left] panel for Precautionary Statements and First Aid

EPA Reg. No.47371-164

EPA Est. No. (as indicated on container)

Net Contents: (as indicated on container)

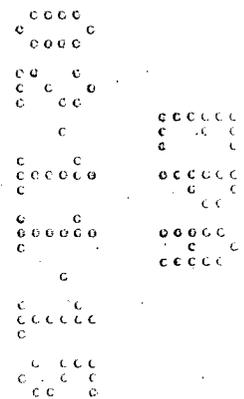
[DOT symbols]

[Country of origin (insert country)]

[Manufactured in (insert country)]

[Barcode]

Manufactured by:
H&S Chemicals Division
c/o Lonza Inc.
90 Boroline Road
Allendale, NJ 07401



DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

DISINFECTANT [1:1000].....	2 oz. per 15½ gallons of water	[500 ppm]
DISINFECTANT [1:909].....	2 oz. per 14 gallons of water	[550 ppm]
SANITIZER [1:3333].....	1 oz. per 26 gallons of water	[150 ppm]
SANITIZER [1:2496].....	1 oz. per 19½ gallons of water	[200 ppm]
SANITIZER [1:1248].....	1 oz. per 9 3/4 gallons of water	[400 ppm]

DISINFECTION / DEODORIZING DIRECTIONS:

If surfaces are visibly dirty, preclean prior to disinfection / deodorizing activity. Prepare a solution of 2 oz. of product per 15½ [or 2 ounces of product per 14 gallons of water] gallons of water. Apply use-solution with a cloth, sponge, mop, coarse trigger sprayer, or by soaking to thoroughly wet all surfaces. For sprayer applications, use a coarse spray device. Spray 6 – 8 inches from the surface, rub with a brush, cloth or sponge. Do not breathe spray. Let solution remain on the surface for a minimum contact time of 10 minutes. Wipe dry with a clean cloth or sponge or allow to air dry. The use solution is prepared fresh for each use then discarded. Rinsing of floors is not necessary unless they are to be waxed or polished. Food contact surfaces must be thoroughly rinsed with potable water.

{Note to reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, one of the following statements must be used:}

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that [1] is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or [2] contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. [This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.]

{or}

This product is not to be used on medical device surfaces.

VIRUCIDAL DIRECTIONS*:

Virucidal against *Bovine rhinotracheitis, *Avian Infectious Bronchitis virus, and *Newcastle Disease virus, *Marek's Disease Virus and *Infectious Bronchitis Virus – Arkansas strain [IBV] according to the virucidal qualification, modified in the presence of 5% organic serum at a 1:1000 dilution. Follow Disinfection Directions.

FUNGICIDAL DIRECTIONS:

Fungicidal against Trichophyton mentagrophytes [and Candida albicans and Aspergillus glaucus] according to the AOAC fungicidal test, modified in the presence of 5% organic serum at a 1:1000 [1:909] dilution. For fungicidal activity use in areas such as locker rooms, dressing rooms, shower and bath areas, and exercise facilities. Follow Disinfection Directions.

MOLD AND MILDEW CONTROL DIRECTIONS: To control mold and mildew on hard, nonporous surfaces wash visible soil from the surface. Then apply a use-solution of 2 fluid oz. per 15½ [or 2 fluid ounces of product per 14 gallons of water] gallons with a mop, sponge, cloth, or coarse trigger sprayer so as to wet all surfaces thoroughly. Let air dry. Repeat application every 7 days to control recurrence of growth.

FISHERY, MILK, CITRUS, ICE CREAM & POTATO PROCESSING PLANTS DISINFECTION DIRECTIONS:

Applied routinely as a disinfectant on walls and floors will reduce or eliminate odors in the processing area. Use on filling equipment to reduce or eliminate odors in the processing area and bacteria associated with condensation on equipment and pipes. Follow Disinfection Directions.

CITRUS CANKER DISEASE CONTROL

For prevention of Citrus Canker Disease through treatment of equipment. Effective against Xanthomonas axonopodis pv. citri [Citrus Canker Disease] at 2000 ppm active quat. Apply treatment to trucks, attached trailers, and field equipment including cargo area, wheels, tires, undercarriage, hood, roof, fenders, and any other hard nonporous equipment taken into infested areas.

Saturate surfaces with a 1:250 use-dilution [5 oz. per 9 3/4 gallons of water [or equivalent dilution]] [2000 ppm active quat] for a period of 10 minutes. Allow to air dry. All surfaces that come in contact with food or crop must be rinsed with potable water before reuse. To prevent the spread of Citrus Canker Disease by this artificial means of transportation, treatments are made by trigger spraying, dipping or brushing. Thoroughly rinse or launder clothing before reuse. Rinse footwear before reuse.

FOR SANITIZING FOOD CONTACT SURFACES:

For use on precleaned, hard, nonporous food contact surfaces including plastic and other hard nonporous cutting boards and chopping blocks, counter tops, tables, food preparation surfaces, cooking and eating utensils and drinking glasses. For heavily soiled areas, remove gross food particles by preflush, prescrape and presoak when necessary. Wash thoroughly with detergent or compatible cleaner then rinse with potable water prior to application of sanitizing solution.

{Note to reviewer: Only one dilution from this table may be used in the paragraphs below}
For Food Contact Surfaces, Food Processing Equipment and Utensils in Dairies and Public Eating Establishments and Food Contact Surfaces, Food Processing Equipment and Utensils in Food Processing Plants [40 CFR 180.940 (a)]:

- 1 oz. per 26 gallons of water [150 ppm quat] [or equivalent dilution]
- 1 oz. per 19 1/2 gallons of water [200 ppm quat] [or equivalent dilution]
- 1 oz. per 9 3/4 gallons of water [400 ppm quat] [or equivalent dilution]
- 2 oz. per 19 1/2 gallons of water [400 ppm quat] [or equivalent dilution]

Use *(insert dilution from table here)* for a minimum contact time of 1 minute in a single application. *{Alternate language for closed loop dilution center:}* Then use product from the Closed Loop Dilution Center *((insert concentration from table here))* for a minimum contact time of 1 minute in a single application.

Apply with a cloth, sponge, mop, coarse trigger sprayer, or by soaking. Eating utensils and drinking glasses must be sanitized by immersion. Thoroughly wet all surfaces. Drain thoroughly and air dry. Do not rinse.

Fresh sanitizing solution must be prepared at least daily or more often if the use solution becomes diluted. For mechanical applications, use solution may not be reused for sanitizing applications but may be reused for other purposes such as cleaning.

Before use as a sanitizer in federally inspected meat and poultry plants and dairies, food products and packaging materials must be removed from the room or carefully protected.

RESTAURANT AND BAR USE:

For use as a sanitizer on dishes, glassware, silverware, eating and cooking utensils. For heavily soiled areas, remove gross food particles by preflush, prescrape and presoak when necessary. Wash thoroughly with detergent or compatible cleaner then rinse with potable water prior to application of this product. Then immerse in a solution of *(insert dilution from table here)* for at least 1 minute. Drain thoroughly and air dry. Do not rinse.

{Alternate language for closed loop dilution system:}

RESTAURANT AND BAR USE:

For use as a sanitizer on dishes, glassware, silverware, eating and cooking utensils. For heavily soiled areas, remove gross food particles by preflush, prescrape and presoak when necessary. Wash thoroughly with detergent or compatible cleaner, then rinse with potable water prior to application of this product. Then immerse in a sanitizing solution from Closed Loop Dilution Center *((insert concentration from table here))* for at least 1 minute. Drain thoroughly and air dry. Do not rinse.

**FOR WISCONSIN ONLY
SANITIZING EATING AND DRINKING UTENSILS IN EATING ESTABLISHMENTS**

1. Scrape and pre-wash utensils and glasses whenever possible.
2. Wash with a good detergent or compatible cleaner.
3. Rinse with potable water.
4. Sanitize in a solution of *(insert a dilution of 200 ppm active or higher dilution from box above here)*. Immerse all utensils for at least two minutes or for a contact time specified by governing sanitary codes.
5. Place sanitized utensils on a rack or drain-board to air dry.
6. Prepare fresh sanitizing solution at least daily or when visibly soiled or diluted.

NOTE: A clean potable water rinse following sanitization is not permitted under Section HFS 196.13 of the Wisconsin Administrative Code.

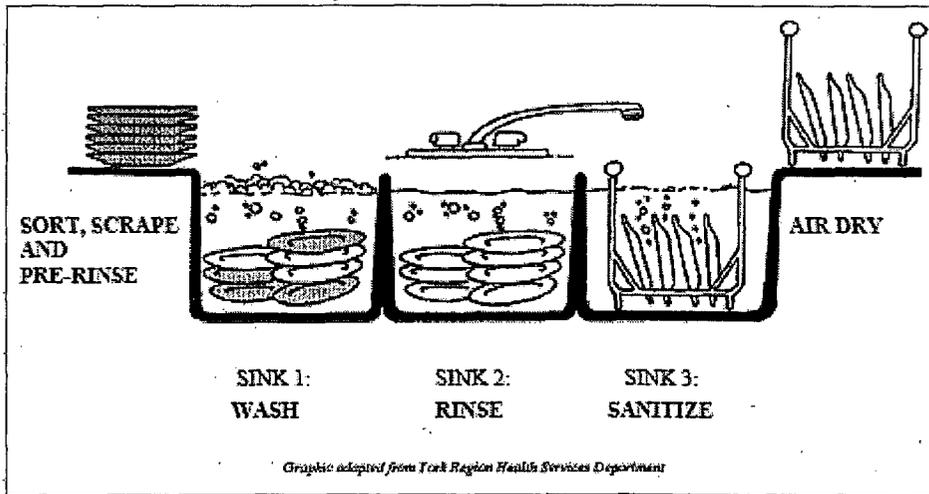
{Alternate language for closed loop dilution center:}

**FOR WISCONSIN ONLY
SANITIZING EATING AND DRINKING UTENSILS IN EATING ESTABLISHMENTS**

1. Scrape and pre-wash utensils and glasses whenever possible.
2. Wash with a good detergent or compatible cleaner.
3. Rinse with potable water.
4. Sanitize in a solution from the Closed Loop Dilution Center (*(insert a dilution of 200 ppm active or higher dilution from box above here)*). Immerse all utensils for at least two minutes or for a contact time specified by governing sanitary codes.
5. Place sanitized utensils on a rack or drain-board to air dry.
6. Fresh sanitizing solution must be prepared at least daily or when visibly soiled or diluted.

NOTE: A clean potable water rinse following sanitization is not permitted under Section HFS 196, Appendix 7-204.11 of the Wisconsin Administrative Code (reference 40 CFR 180.940).

{Note to reviewer: The following graphic or a graphic of similar content may accompany any of the above food contact sanitization sections}



BEVERAGE PLANTS:

For sanitizing of bottling or pre-mix dispensing equipment. After cleaning, thoroughly rinse equipment with cold or lukewarm water. Fill equipment with solution of *(insert dilution from table here)*. Allow the solution to remain in contact with equipment for at least 1 minute or until operations resume at which time the sanitizing solution must be drained from the system. To insure the removal of flavors, it is suggested that during changeover between products the system should be cleaned, rinsed and flushed with the sanitizing solution for at least 1 minute. Allow to drain completely before using. Do not rinse.

SANITARY FILLING:

For use in sanitizing bottles or cans in the final rinse application. The product is to be proportioned into the final rinse water line of the container washer or rinser in *[at a]* concentration of *(insert dilution from table here)*. A sanitizing solution of *(insert dilution from table here)* must be used in an external application for the filler and closing machine. Do not rinse.

Formulation HS-1210 Disinfectant / Sanitizer (50%)
EPA Reg. No. 47371-164
EPA Stamped Label 11-5-2012, draft Notification 2-10-2015

STORAGE TANK SANITIZING:

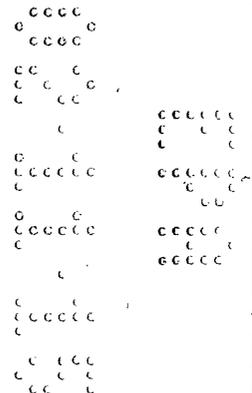
For sanitizing beer fermentation and holding tanks. A solution of (insert dilution from table here) must be applied manually or used in combination with automated cleaning systems. Follow directions for sanitizing food contact surfaces. Drain thoroughly. Do not rinse. For mechanical operations or automated systems, the used sanitizing solution may not be reused for sanitizing but may be reused for other purposes such as cleaning.

FOR SANITIZING IN FISHERIES, MILK, CITRUS, POTATO & ICE CREAM PROCESSING PLANTS:

For use as a sanitizer on conveyors and equipment to reduce or eliminate odors in the processing area. Also, for use on filling equipment to reduce bacteria associated with condensation on equipment and pipes. Follow directions for sanitizing food contact surfaces.

TO SANITIZE [ICE MACHINES] [[BEVERAGE] [SOFT SERVE ICE CREAM] [AND OTHER FOOD] DISPENSING EQUIPMENT]:

1. Turn off equipment
2. Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing.
3. Apply a solution of (insert appropriate dilution from dilution chart) [or equivalent dilution] by mechanical spray, directly pouring and or by recirculating through the [equipment] system.
4. Allow surfaces to remain wet or solution to remain in equipment for at least 60 seconds.
5. Drain equipment thoroughly and allow to air dry before reuse.



{Note to reviewer: The following are optional text and graphics}

{For Bag-in-Box Containers:}

For Bag – In – Box Containers:

How to use this package:

This package is designed to be used with dilution control systems only. Open package and connect to dispense according to directions on box top.

Trigger Sprayers:

Fill bottle from dispenser.

Apply to surfaces as specified in directions above.

Mop Buckets:

Fill bucket from dispenser.

Set up "Wet Floor" signs.

Mop floor surface as specified in directions above

<p>OPENING INSTRUCTIONS</p> <ol style="list-style-type: none"> 1. Position box with perforation up. 2. Press in circle. 3. Lift flap/ear along perforation. 4. Retrieve fitting on bag. 5. Remove clear dust-cap from bag fitting. 6. Twist dispenser connector onto bag fitting. 7. Place bag-in-box into position on dispenser shelf. 8. Close dispenser (if applicable). 		<p>INSTRUCCIONES PARA ABRIR</p> <ol style="list-style-type: none"> 1. Ponga la caja con la perforación hacia arriba. 2. Empuje el círculo hacia adentro. 3. Levante la pestaña arrancándola de la caja a lo largo de la perforación. 4. Saque el adaptador que está en la bolsa. 5. Quite la tapa transparente contra el polvo que tiene el adaptador de la bolsa. 6. Enrosque el conector de dispensador al adaptador. 7. Ponga la "bag-in-box" (bolsa en caja) en posición en el mezclador de despacho. 8. Cierre el dispensador (si corresponde).
--	--	---

{Note to reviewer. The following may be used only if the supplemental registrant has obtained an NSF listing. Allowed on back or side panel only.}

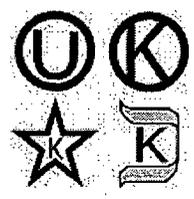


{or}

[NSF Listed]
[[Insert NSF 6-Digit Listing Number here]]



{Note to reviewer. The following may be used only if the supplemental registrant has obtained a Kosher Certification.}



{Any Kosher Symbol such as:}

[Kosher]

